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under 35 U.S.C. §103(a) as being unpatentable over Buckley et al. (U.S. 5,281,186) and further in view of Allen (U.S. 6,361,806).

Claim 1 is directed to a breast pad for absorbing fluid leaking from the breast of a woman and minimizing the soiling of clothing worn by the woman. The breast pad has a front side which faces the breast and a back side which faces the clothing. The front side comprises from about 0.1 g/m<sup>2</sup> to about 30 g/m<sup>2</sup> of a composition for improving breast and nipple skin health. The composition comprises omega-3 fatty acids.

As discussed during the interview, Buckley et al. is directed to a protective breast cup arrangement comprising a plurality of breast cup members arranged to provide protection to an individual's breast region during sporting events. The cup arrangement may include a nipple pad formed from a lotion impregnated fluid absorbent sponge material. The lotion is of any type commercially available to afford protection and healing to an individual's skin or nipple.

Significantly, Buckley et al. fail to disclose a breast pad comprising from about 0.1 g/m<sup>2</sup> to about 30 g/m<sup>2</sup> of a composition for improving breast and nipple skin health comprising omega-3 fatty acids. This is a requirement of claim 1 and is an important aspect of Applicants' invention. Recognizing that Buckley et al. fail to make such a disclosure, or make any specific disclosure regarding the composition, the Office cites Allen for combination with Buckley et al. in an attempt to find each and every element of Applicants' claim 1.

Allen discloses topical emollient compositions and methods that allow for topical administration of a balanced mixture of C<sub>18</sub> unsaturated fatty acids that is effective to penetrate epithelial barriers and stimulate changes in fatty acid

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metabolism in subcutaneous adipose tissues. The compositions consist of hydrophilic:hydrophobic emulsions comprising a carrier, a vehicle, a compatible balanced fatty acid penetrant consisting of  $C_{16:0}$ ,  $C_{18:0}$  and  $C_{18:1}$  fatty acid derivatives, a mixture of medicinal fatty acids, a natural anti-inflammatory compound, a natural analgesic compound, a natural estrogenic compound, and a fragrance. In one embodiment, the composition may comprise an alpha linoleic omega-3 fatty acid. The composition is suitably applied to breast adipose tissues to improve cometic appearance such as an increase in size or shape, and a decrease in sagging.

In combining these references, the Office states that it would have been obvious to one of ordinary skill in the art to modify the breast pad of Buckley et al. to provide the composition taught by Allen because the composition of Allen promotes improvement of the skin.

As noted in the interview, in order for the Office to show a *prima facie* case of obviousness, M.P.E.P. § 2143 requires that the Office meet three criteria: (1) the prior art reference(s) must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and (3) there must be some reasonable expectation of success. Applicants assert that the Office has not, and cannot, meet the burden of number (2) above, which requires the Office to show some motivation to combine the cited references.

When looking for some suggestion or motivation to combine or modify the references, the mere fact that references can be

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combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

A close reading of the references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the Buckley et al. and Allen references would not have been made.<sup>1</sup> Therefore, Applicants assert that the Office clearly failed to meet its burden under the second prong set forth above as there is no motivation to combine Buckley et al. and Allen to arrive at the instant invention; and further, that a careful reading of the Allen reference actually teaches away from use of their composition on a breast pad as discussed below.

As discussed in the telephone interview on January 22, 2004, Applicants make two points in arguing that there is no motivation to combine the Buckley et al. reference with the Allen reference. First, claim 1 requires that the front side of the breast pad comprise an omega-3 fatty acid. As discussed in the specification, the omega-3 fatty acid-containing composition is

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<sup>1</sup>MPEP §2142 further provides that in order to reach a proper determination under 35 U.S.C. 103, the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.

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introduced onto the breast pad such that it contacts the surface of the breast and nipple skin during use so that it can help repair skin damage on the skin surface (stratum corneum) induced by suckling by providing lipids lost from the skin surface. One skilled in the art would clearly recognize that for a composition located on a breast pad to improve the health of the nipple and skin tissue, it must contact and remain on the same. In direct contrast, the composition of Allen is specifically designed to penetrate epithelial barriers and stimulate changes in fatty acid metabolism in subcutaneous adipose tissues; that is, the Allen composition is designed not to remain on and to treat the stratum corneum, but rather to penetrate through four layers of skin: (1) the stratum corneum (the lipid-containing layer of skin), (2) the epidermis, (3) the dermis, and (4) the underlying adipose tissue where the composition can stimulate changes in fatty acid metabolism. Instead of working on the surface of the skin like the composition of claim 1, the Allen composition is specifically designed to penetrate many layers of skin deep into the adipose tissue. To this end, the Allen composition comprises a penetrant, or penetration enhancing agent, effective to increase the penetration of the emulsion into the subcutaneous tissues. The penetration enhancing agent will not allow the Allen composition to remain on the stratum corneum layer of the skin. This is in direct contrast to an application of a composition for skin repair on the surface of the skin as the composition set forth in claim 1 seeks to do.

Because the compositions of Allen comprise a penetrant and are designed to penetrate numerous layers of skin (and therefore are not designed or intended to treat the outer layer of the skin, i.e., the stratum corneum), one skilled in the art would

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have clearly recognized that the compositions of Allen are not suitable for use on a breast pad to improve breast and nipple skin health during breast feeding. The Allen compositions simply penetrate through the outer layers and deep into the skin and thus would not be of value on the stratum corneum. One skilled in the art and reading Allen would not, and could not, have been motivated to utilize the composition on a breast pad for treating the skin by replacing lipids on the outer layer of the skin as the Allen composition is designed to penetrate deeply into the subcutaneous layers. As such, motivation to combine these references would have been lacking.

Applicants' second point for finding a lack of suggestion or motivation to combine the Buckley et al. and Allen references is that one skilled in the art and considering the Allen reference would also have easily realized that the compositions of Allen are not suitable for use on a breast pad because of serious health concerns to both the mother, and the nursing infant. As mentioned in Applicants' specification and easily recognized and understood by one skilled in the art, the omega-3 fatty acid comprising composition introduced onto the breast pad will, to some extent, be ingested by the suckling infant as the composition is transferred from the breast pad to the breast and nipple skin to facilitate repair of skin. The composition as set forth in claim 1 is designed for this certainty as it does not comprise any components that could be harmful if ingested by the infant and, may actually improve the health of the infant through the ingestion of the omega-3 fatty acids. In contrast, the composition of Allen is strictly for topical application, as mentioned throughout their disclosure, and is not designed for ingestion. There is no mention that the composition of Allen

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could be ingested by an infant, or anyone, without potential harm. By way of example, as set forth in Example 1, Table A, the Allen composition may comprise sodium borate which, if ingested by an infant, can result in vomiting, diarrhea, shock and even death. Clearly, such a composition was not designed for use on a breast pad where the composition could ultimately be ingested by a nursing infant. This is easily recognizable to one skilled in the art.

Additionally, the compositions of Allen comprise a natural estrogen compound. The introduction of an estrogen or estrogen producing compound into the tissue of a lactating mother can be dangerous to the health of the mother, and to the suckling infant. A close reading of the Allen reference by one skilled in the art leads to the inevitable conclusion that many of the chemical components suitable for use in the Allen composition for topical application are not suitable for ingestion by a sucking infant, which will happen if the composition is introduced onto a breast pad and transferred to the breast of the mother. Therefore, one skilled in the art would not have looked to the Allen composition for use on a breast pad.

With all due respect, it appears that the Office has used improper hindsight analysis and reconstruction when combining the Buckley et al. and Allen references. The Federal Circuit has repeatedly cautioned against hindsight analysis and held that such practice is improper. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988). Based on the foregoing, the combination of references by the Office is improper as there is no motivation or suggestion to make the combination by one skilled in the art. As such, claim 1 is patentable.

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Claims 1-16 depend from claim 1 and are patentable for the same reasons as claim 1, as well as for the additional elements they require.

Claim 17 is similar to claim 1 with the additional requirement that the composition further comprise omega-6 fatty acids. Claim 17 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 18-34 depend from claim 17 and are patentable for the same reasons as claim 17, as well as for the additional elements they require.

Claim 35 is similar to claim 1 with the additional requirement that the composition comprise essential fatty acids. Claim 35 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 36-52 depend from claim 35 and are patentable for the same reasons as claim 35, as well as for the additional elements they require.

Claim 53 is similar to claim 1 and requires that the composition comprise flaxseed oil. Claim 53 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claims 54 and 55 depend from claim 53 and are patentable for the same reasons as claim 53, as well as for the additional elements they require.

Claim 56 is similar to claim 1 wherein the composition comprises linoleic acid, alpha linoleic acid, eicosapentenoic acid, and docosahexenoic acid. Claim 56 is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

Claim 57 depends from claim 56 and is patentable for the

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same reason as claim 56, as well as for the additional elements it requires.

Claim 58 is directed to a method of treating or preventing nipple tenderness and cracking comprising introducing a composition comprising omega-3 fatty acids onto a breast pad and transferring the composition from the breast pad to the breast of the wearer. Claim 58 is similar to claim 1 and is patentable for the same reasons as claim 1, as well as for the additional elements it requires.

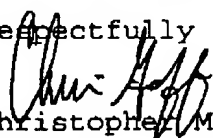
Claims 59-64 depend from claim 58 and are patentable for the same reasons as claim 58, as well as for the additional elements they require.

Claim 65 is similar to claim 58 and is patentable for the same reasons as claim 58, as well as for the additional elements it requires.

Claims 66-71 depend from claim 65 and are patentable for the same reasons as claim 65, as well as for the additional elements they require.

In view of the above, applicants respectfully request favorable reconsideration and allowance of all pending claims. The Commissioner is hereby authorized to charge any fee deficiency in connection with this Letter to Deposit Account Number 19-1345 in the name of Senniger, Powers, Leavitt & Roedel.

Respectfully Submitted,

  
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